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Paper 120  
ENTERED: 22 September 2010

UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference No. 105,496

CALIFORNIA INSTITUTE OF TECHNOLOGY  
(5,821,058),  
Junior Party,

v.

ENZO LIFE SCIENCES, INC.  
(08/486,069),  
Senior Party.

Before SALLY GARDNER LANE and RICHARD TORCZON and  
MICHAEL P. TIERNEY, *Administrative Patent Judges*.

TORCZON, *Administrative Patent Judge*.

DECISION

Bd.R. 125  
on motions

The junior party (CIT) has nine motions pending. The senior party  
(Enzo) has four motions pending.

CIT motion 4 (written description, some Enzo claims) is GRANTED;

CIT motion 7 (late claiming bar, some Enzo claims) is GRANTED;

the decision on CIT motion 12 (exclude testimony) has been reconsidered, but further relief is DENIED;

Enzo motion 1 (undesignate remaining Enzo claims) is GRANTED;  
and

CIT motions 3, 5, 6, 8-10 and Enzo motions 2-4 are DISMISSED as moot.

### OPINION

#### I. INTRODUCTION

The count<sup>1</sup> for this interference defines the contested subject matter in terms of the method of CIT's claim 14:<sup>2</sup>

A method of determining the sequence of a polynucleotide by analyzing polynucleotide fragments generated by a polynucleotide sequencing technique, each of said polynucleotide fragments being tagged with a chromophore or fluorophore, comprising;

introducing the tagged polynucleotide fragments into an electrophoretic medium;

separating the tagged polynucleotide fragments in said electrophoretic medium using an electrophoretic procedure capable of resolving said polynucleotide fragments differing in length by a single nucleotide;

detecting the separated tagged polynucleotide fragments by means of the chromophore or fluorophore; and

determining the polynucleotide sequence from the polynucleotide fragments detected.

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<sup>1</sup> Paper 1 (Declaration) at 3.

<sup>2</sup> Paper 5 (CIT clean claims) at 4-5.

CIT has filed two nominally threshold motions, seeking judgment of a lack of written description and a bar under 35 U.S.C. 135(b)(1) against a subset of the claims.<sup>3</sup> Enzo moves to have the other claims designated as not corresponding to the count.<sup>4</sup> CIT's threshold motions do not directly address the other claims and CIT does not oppose Enzo's motion. If Enzo's unopposed motion and either of CIT's threshold motions were granted, then the Enzo would no longer have claims that interfere with CIT's claims.

## II. CIT MOTION 4—WRITTEN DESCRIPTION

### A. Introduction

CIT moves for judgment that Enzo's involved claims lack written description required under 35 U.S.C. 112(1).<sup>5</sup> Enzo opposes.<sup>6</sup> The parties stipulate that the question may be resolved on the basis of independent claims 569, 721, 1767, 1776, and 1777, as well as seventeen dependent claims.<sup>7</sup> The parties have agreed that subsequent case law developments relating to written description in interferences do not affect the issues in this interference.<sup>8</sup>

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<sup>3</sup> Bd.R. 201, "Threshold issue"; Paper 43 (CIT Mot. 4, written description); Paper 46 (CIT Mot. 7, § 135(b) bar).

<sup>4</sup> Paper 37 (Enzo Mot. 1).

<sup>5</sup> Paper 43 at 1.

<sup>6</sup> Paper 71 (Enzo Opp.).

<sup>7</sup> Paper 43 at 3 n.1 & text. It is appropriate to focus on the contested limitations. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1256 (Fed. Cir. 2007); *Gechter v. Davidson*, 116 F.3d 1454, 1460 (Fed. Cir. 1997).

<sup>8</sup> Paper 116 (Order canceling telephone hearing), noting the parties had declined an opportunity to brief *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366 (Fed. Cir. 2009), and explaining the parties had thus waived any argument based on *Agilent*.

### B. Facts and enumerated findings

All of the representative claims require providing or generating multiple labeled nucleic acid fragments, separating or resolving those labeled fragments in a sequencing gel, and detecting those labeled fragments.<sup>9</sup>

Claims 569, 721, and 1776 define processes "for determining the sequence of a nucleic acid of interest" using a sequencing gel. Claims 1767 and 1777 define processes "for detecting non-radioactively labeled nucleic acid fragments with a sequencing gel".<sup>10</sup> According to Enzo, detecting nucleic acid fragments on a sequencing gel necessarily involves determining the sequence of the fragment.<sup>11</sup>

CIT notes that Enzo's disclosure summarizes the invention as follows:<sup>12</sup>

In accordance with the practices of this invention nucleotides are modified, such as at the 5 position of pyrimidine or the 7 position of purine, preparatory for the preparation therefrom of nucleotide probes suitable for attachment to or incorporation into DNA or other nucleic acid material. In the practices of this invention nucleotides, i.e. nucleic acids, preferably are modified in a nondisruptive manner such that the resulting modified nucleotides are capable of incorporation into nucleic acids and once incorporated...do not significantly interfere with the formation or stabilization of the double helix formed of the resulting nucleic acids containing the modified nucleotides.

At pages 27 to 38, Enzo's disclosure discusses several types of reactions involving the detection of complexes of probes hybridized to

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<sup>9</sup> Paper 71, apdx. 2, admitted fact 17.

<sup>10</sup> Paper 10 (Enzo clean claims).

<sup>11</sup> Paper 71, apdx. 2, admitted facts 15 & 16.

nucleic acids of interest; detecting specific nucleic acids in chromosomes or fixed cells or tissue sections, gene mapping and recombinant DNA technologies, detecting certain sequences in clinical samples, diagnosis of etiological agents, screening bacteria for antibiotic resistance, diagnosing genetic disorders, chromosomal karyotyping, and detecting tumors.<sup>13</sup>

The only express reference in the disclosure to "sequencing" occurs in a paragraph on page 84, which discloses in its entirety (emphasis added):<sup>14</sup>

This type of self-signaling molecule can be used to monitor any nucleic acid hybridization reaction. It is particularly important for detecting nucleic acids in gels (for example, *sequencing gels*).

On its face, the paragraph appears to disclose hybridization reactions. The first sentence identifies the use of self-signaling molecules "to monitor *any* nucleic acid hybridization reaction" (emphasis added). The second sentence appears to illustrate a particular example within the scope of first sentence. There is no transitional phrase suggesting that the second sentence involves a different topic. If the second sentence were intended as a disclosure of a sequencing invention, then it would be a non sequitur.

CIT provided testimony from Larry Gold, a professor, inventor and entrepreneur in biotechnology.<sup>15</sup> Dr. Gold testified that one skilled in the art would have understood the paragraph on page 84 to convey that—<sup>16</sup>

the self-signaling nucleic acids can be used as probes to detect the presence of a nucleic acid hybridization reaction in a gel

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<sup>12</sup> Paper 71, apdx. 2, admitted fact 30.

<sup>13</sup> Paper 71, apdx. 2, admitted fact 30.

<sup>14</sup> Exh. 2041 at 84.

<sup>15</sup> Exh. 2046 (Gold decl'n), ¶4.

<sup>16</sup> *Id.*, ¶26.

and would not have conveyed determining the sequence of a nucleic acid of interest. In particular, the first sentence of the paragraph discusses monitoring a nucleic acid hybridization reaction. In my opinion, that sentence would have conveyed to one skilled in the art detecting the presence or absence of a double-stranded complex of a labeled probe hybridized to a complementary nucleic acid of interest. As I noted above, the Specification repeatedly discusses such methods of detecting or monitoring hybridization reactions.

[1] Dr. Gold's testimony is facially credible and consistent with the plain meaning of Enzo's disclosure.

[2] The paragraph parenthetically mentioning "sequencing gel" is not a disclosure of sequencing.

Enzo responds that use of hybridization probes is just one embodiment of its invention, as other portions of the disclosure show. Further, the parenthetical reference to sequencing gels is inconsistent with CIT's reading, but not inconsistent with Enzo's reading. Finally, the skill in the art would provide the missing steps.<sup>17</sup>

CIT has not shown how Enzo's disclosure expressly limits the invention to the use of hybridization probes. Indeed, the disclosure discusses detection generally.<sup>18</sup> Significantly, however, Enzo does not point to any further express or implied disclosure of sequencing other than the paragraph discussed above.

Enzo argues that sequencing and hybridization are not mutually exclusive.<sup>19</sup> Enzo relies on the testimony of Bruce A. Roe. Dr. Roe is a

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<sup>17</sup> Paper 71 at 2.

<sup>18</sup> *Id.* at 8-9.

<sup>19</sup> *Id.* at 11.

professor and researcher in biochemistry, specifically including nucleic acid chemistry.<sup>20</sup> Dr. Roe explains that every step of Enzo's representative claims was found in the prior art, except that Enzo used non-radioactive labels.<sup>21</sup> Moreover, Dr. Roe testified—<sup>22</sup>

The distinction between a labeled polynucleotide which is "hybridized" as being distinct from one that would be employed in a sequencing method is somewhat of a red-herring. In fact, during DNA sequencing, labeled oligonucleotides do undergo hybridization with target sequences in the course of forming the different length labeled chains, but that is prior to and separate from their resolution on a sequencing gel. Although the examples and the preferred embodiment of the '069 application provide a detailed description relating to detection by hybridization, it is manifest that this is explicitly set forth as one preferred embodiment. Sequencing and hybridization are not mutually exclusive.

[3] Dr. Roe's testimony on this point is credible.

[4] Sequencing in general was at the time of filing already known in the art.

[5] Dr. Roe's testimony does not support a finding that those skilled in the art would have understood that Enzo intended to disclose a sequencing invention.

[6] The Enzo disclosure considered as a whole would not have conveyed possession of a sequencing invention.

### C. Analysis

"Inventors, before they can receive a patent, are required to file in the Patent Office a written description of their invention, and of the manner and

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<sup>20</sup> Exh. 1024, 1st Roe decl'n.

<sup>21</sup> Exh. 1056, 2d Roe decl'n, ¶11.

process of making and using the same, in such full, clear, concise, and exact terms as to enable any person skilled in the art to make, construct, and use the same."<sup>23</sup> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.<sup>24</sup> The specification need not provide literal support for the claimed subject matter at issue, but it must convey with reasonable clarity to those skilled in the art that the inventor possessed the invention. "Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims."<sup>25</sup>

Proving a lack of written description requires proving a negative, so the movant may satisfy its burden of production in the first instance by demonstrating that a contested limitation is missing in the disclosure.<sup>26</sup> The applicant, after all, has the legal obligation to provide an adequate written description.<sup>27</sup> The opponent must identify the precise location in the

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<sup>22</sup> *Id.*, ¶17.

<sup>23</sup> *Bates v. Coe*, 98 U.S. 31, 34 (1878); 35 U.S.C. 112(1); accord *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 121 (1853) (explaining that an applicant may "claim only what he has invented and described").

<sup>24</sup> *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997).

<sup>25</sup> *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000).

<sup>26</sup> See *Hyatt v. Dudas*, 492 F.3d 1365, 1370-71 (Fed. Cir. 2007) (written description), citing *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (written description); *Biotec Biologische Naturverpackungen v. Biocorp., Inc.*, 249 F.3d 1341, 1354 (Fed. Cir. 2001) (holding testimony may discharge a negative burden).

<sup>27</sup> *Hyatt*, 492 F.3d at 1370.



specification where the relevant disclosure occurs.<sup>28</sup> Since the test relies on what those skilled in the art would have understood, testimony is often pivotal in evaluating a written description proof.<sup>29</sup>

In the present case, hybridization is the focus of Enzo's disclosure, but the disclosure is not expressly limited to hybridization. Moreover, those of skill in the art would have certainly been aware of nucleotide sequencing. The possibility of an unstated invention is not disclosure, however. It would make no sense to say written description is satisfied by a simple failure to exclude.<sup>30</sup> Indeed, even disclosure sufficient to render an invention obvious is not by that fact sufficient to disclose the invention.<sup>31</sup>

Enzo attacks CIT's attempt to explain the anomalous "sequencing gel" reference as consistent with hybridization. CIT's explanation is weak for the reasons Enzo provides. This weakness does not help Enzo, however, since it does not show that the reference could only be about sequencing either. Indeed, one skilled in the art could be forgiven for taking a single, parenthetical reference to sequencing gels in a paragraph otherwise about hybridization on page 84 of a 110 page disclosure to be simply a mistake.

Dr. Roe's testimony, to the extent it is entitled any weight, would not compel a different result. His testimony about the great skill in the art, even

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<sup>28</sup> *Id.* at 1371.

<sup>29</sup> *Alton*, 76 F.3d at 1174-75.

<sup>30</sup> Indeed, such a position would be Constitutionally questionable since silence is unlikely "[t]o promote Progress of...useful Arts". U.S. Const., art. I, § 8, cl. 8.

<sup>31</sup> *Goeddel v. Sugano*, slip op. at 13 (Fed. Cir., 7 Sept. 2010) (<http://www.cafc.uscourts.gov/images/stories/opinions-orders/09-1156-1157.pdf>); *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1340 (Fed. Cir. 2010).

if adopted, cannot create disclosure. Similarly, his testimony against CIT's weak explanation for the meaning of "sequencing gel" cannot make up for the equally weak (and terse, ambiguous and anomalous) disclosure of "sequencing gel" in the disclosure. The purpose of expert testimony is to elucidate what the disclosure actually says, not to provide what it does not say.<sup>32</sup>

#### D. Holding

It is more likely than not that one of skill in the art would think that Enzo did not disclose a sequencing invention.

### III. CIT MOTION 7—STATUTE OF REPOSE

#### A. Introduction

CIT moves for judgment that Enzo's involved claims are barred under § 135(b)(1)<sup>33</sup> in view of the claims in a prior patent to Smith (534 patent), which is not involved in the interference.<sup>34</sup> Under the statute:

A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

Since the Smith patent issued 15 December 1992, the critical date under the statute for Enzo's claims is 15 December 1993. Claims 569, 707-14, 721,

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<sup>32</sup> Cf. *Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1300-02 (Fed. Cir. 2005) (affirming decision giving little weight to uncontroverted testimony on corresponding structure where specification gives minimal support for testimony).

<sup>33</sup> Paper 46 at 1.

<sup>34</sup> L.M. Smith, L.E. Hood, M.W. Hunkapiller & T.J. Hunkapiller, *Automated DNA sequencing technique*, U.S. Pat. 5,171,534 (iss'd 15 Dec. 1992).

859-66 and 871 are said to be representative.<sup>35</sup> As a threshold matter, however, the parties have briefed the question of whether the motion even raises a "threshold issue".

#### B. Threshold issue

The rules define "threshold issue" to mean "an issue that, if resolved in favor of the movant, would deprive the opponent of standing in the interference." The list of examples includes "Repose under 35 U.S.C. 135(b) in view of the movant's patent or published application".<sup>36</sup> Significantly, the rule uses the word "repose" rather than "bar". As the legal understanding of this provision has evolved, it has come to be understood as both a repose and a bar.

The history of the principles underlying § 135(b)(1) is complex. In *Chapman v. Wintroath*,<sup>37</sup> the Supreme Court reviewed litigation arising from a patent interference. Chapman had copied claims almost twenty months after Wintroath's patent issued, although Chapman had filed his application before Wintroath.<sup>38</sup> Wintroath argued that Chapman should be estopped. The Court accepted the legitimacy of a late-claiming estoppel, but reversed after concluding that the proper period for the estoppel was two years, which was then the statutory limit for antedating anticipatory prior art.<sup>39</sup> Although the court explicitly treated the issue as one of estoppel in an interference, its reasoning was based on a patentability statute.

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<sup>35</sup> Paper 46 at 8.

<sup>36</sup> Bd.R. 201, "Threshold issue".

<sup>37</sup> 252 U.S. 126 (1920).

<sup>38</sup> *Id.* at 132.

<sup>39</sup> *Id.* at 138-39. The present bar date in § 135(b)—one year—again corresponds to the anticipation bar date in § 102(b).

In *Webster Electric Company v. Splitdorf Electrical Company*,<sup>40</sup> the issue arose in the context of an infringement suit, based on a third-party patent with an ambiguous relationship to the parties.<sup>41</sup> Webster had copied claims to provoke an interference with the third party. Webster lost the interference, but subsequently filed broader claims that were allowed and formed the basis for the infringement claim.<sup>42</sup> Thus, in *Webster*, there was no question of repose during an interference. If anything, it was more of an estoppel arising out of an interference.<sup>43</sup> In any case, the Court treated the issue as a late-claiming estoppel similar to the statutory time limit for broadened claims in a reissue application.<sup>44</sup> The reissue estoppel is treated as a patentability issue.<sup>45</sup>

Congress enacted a version of the estoppel in a section governing ex parte examination,<sup>46</sup> which suggests a patentability bar. The legislative history, however, focused on the repose aspect:<sup>47</sup>

A patent may be out and in use for several years and the patentee feel secure in his property, yet at any time he may have the burden and expense of an interference thrust upon him, with the possibility that he may even lose his patent.

This concern for repose is personal to the patentee drawn into the burden and expense of an interference.

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<sup>40</sup> 264 U.S. 463 (1924).

<sup>41</sup> *Id.* at 464.

<sup>42</sup> *Id.* at 464-65.

<sup>43</sup> See Bd.R. 127(a).

<sup>44</sup> *Id.* at 465-66.

<sup>45</sup> *In re Graff*, 111 F.3d 874, 875, 877 (Fed. Cir. 1997).

<sup>46</sup> 53 Stat. 1213 (1939), amending R.S. § 4903.

<sup>47</sup> H. Rep. No. 970, 76th Cong., 1st Sess. at 1 (1939).

Subsequently, the Office treated the late-claiming estoppel now in § 135(b)(1) as a basis for rejection.<sup>48</sup> Case law also, however, treated it as a basis for repose during an interference.<sup>49</sup> In 1980, the Court of Customs and Patent Appeals said the estoppel was *not* a basis for a rejection,<sup>50</sup> but the Court of Appeals for the Federal Circuit later explained that this limitation on the use of the estoppel as a rejection was simply dicta.<sup>51</sup>

A statute of repose is different from a statutory bar. Both may constitute an absolute bar on further action by a party, but the statutory bar is general in scope, whereas repose protects the interests of a targeted party. For example, in a recent securities decision, the Supreme Court explained:<sup>52</sup>

But Congress' inclusion in the statute of an unqualified bar on actions instituted "5 years after such violation,"...giving defendants total repose after five years, should diminish that fear.

In *Strelchenko v. Campbell*,<sup>53</sup> Judge Schafer emphasized the repose aspect in declining to treat a motion for judgment under § 135(b)(1) as a threshold motion. Campbell sought judgment based on a patent to a third-party not involved in the interference. In *Berman v. Housey*, the Federal Circuit had endorsed and even encouraged treating § 135(b)(1) as a

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<sup>48</sup> E.g., *In re Sitz*, 331 F.2d 617, 625, (CCPA 1964) (affirming rejection); *Hartford-Empire Co. v. Coe*, 76 F.2d 426, 427 (D.C. Cir. 1935) (upholding rejection as "fatal laches").

<sup>49</sup> E.g., *Corbett v. Chisholm*, 568 F.2d 759, 765 (CCPA 1977).

<sup>50</sup> *In re Sasse*, 629 F.2d 675, 680-81 (CCPA 1980).

<sup>51</sup> *In re McGrew*, 120 F.3d 1236, 1239 (Fed. Cir. 1997).

<sup>52</sup> *Merck & Co., Inc. v. Reynolds*, \_\_ U.S. \_\_, 130 S. Ct. 1784, 1797 (2010).

<sup>53</sup> <http://www.uspto.gov/ip/boards/bpai/decisions/inform/104809-026.pdf>, 2002 WL 1300267 (BPAI 2002) (order).

threshold issue leading to the termination of an interference without resolving other patentability issues.<sup>54</sup> Judge Schafer distinguished *Berman*, noting that the patents creating the bar for Berman were two of Housey's three involved patents. He concluded that in Campbell's motion § 135(b) was simply a patentability bar rather than an effort to give repose to the third-party patentee.

CIT argues that the two Smith patents would have issued as a single patent but for an Office imposed restriction requirement. Moreover, CIT argues that its facts are similar to those in *Berman*.<sup>55</sup> Enzo argues that repose based on the uninvolved Smith patent would be unjust because CIT obtained statutory protection from a double-patenting rejection by virtue of the compelled restriction. Moreover, Enzo argues that *Berman* is distinguished by the fact that the Housey patents providing the basis for the estoppel were also involved in the interference.

The rule defining threshold issue explicitly requires the patent forming the basis of the estoppel to be "the movant's patent",<sup>56</sup> and is thus narrower than the statutory bar,<sup>57</sup> which may be based on a patent to anyone else granted more than a year before the claim was filed. The rule does not expressly address whether the patent must be an "involved"<sup>58</sup> patent. The commentary to the final rule, however, notes that repose is "personal" to the

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<sup>54</sup> 291 F.3d 1345, 1352 (Fed. Cir. 2002).

<sup>55</sup> Paper 46 at 2-4.

<sup>56</sup> Bd.R. 201, "Threshold issue".

<sup>57</sup> Final Rule, *Rules of Practice Before the Board of Patent Appeals and Interferences*, 69 Fed. Reg. 49960, 49991 (2004) (Comment 162 & Answer).

<sup>58</sup> Bd.R. 100: "*Involved* means the Board has declared the...patent...so described to be a subject of the contested case."

patentee. Moreover, the commentary suggests that the patent in question must be the involved patent inasmuch as it says the bar:<sup>59</sup>

is intended to provide a patentee...repose from any attack more than one year after issuance...of the interfering claim.

Since only the patentee's involved claim is an issued, interfering claim, it follows that the rule contemplates that the patent in question should be the involved patent.

The facts of this case illustrate the wisdom of the "involved patent" interpretation. While Enzo argues that it is unjust that CIT obtain both repose and the benefit of the restriction requirement, a different inequity is more salient. CIT wishes to obtain repose for a patent that is not in fact at risk.<sup>60</sup> The history of the repose provision discussed above shows that it is grounded in equitable principles. Having one's cake and eating it too rarely falls under the heading of equity. On the facts of this case, CIT could not reasonably expect repose based on its uninvolved patent.<sup>61</sup> Hence, the issue is not a threshold issue and would not be appropriate for expedited consideration.

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<sup>59</sup> Final Rule at 49991 (Comment 162 & Answer).

<sup>60</sup> Paper 74 (Enzo Opp. 7) at 11-14 (noting that CIT has not moved to add the uninvolved Smith patent to the interference).

<sup>61</sup> Cf. *Malm v. Schneider*, 101 F.2d 201, 203 (CCPA 1939) (holding in a pre-statutory bar era that a foreign patent to the junior party created a question of patentability, but not of estoppel) (distinguishing *Hartford-Empire Co.* and *Webster Elec. Co.*).

Although CIT has not established that its motion raises a threshold issue, it nevertheless raises a patentability issue.<sup>62</sup> The board always has discretion to reach a patentability question in an interference.<sup>63</sup> In the present case, the parties have already fully briefed the merits, which strengthens the case for reaching the patentability question. In addition to disputing whether repose is properly a threshold issue, the briefing has centered on whether the earlier Smith patent, which is not involved in the interference, is even relevant.

### C. Facts and enumerated findings

The parties have agreed to have the merits decided on the basis of representative claims.<sup>64</sup>

The earlier Smith patent issued on 15 December 1992.<sup>65</sup> The representative claims were all added after 15 December 1993.<sup>66</sup>

[7] The critical date for § 135(b)(1) based on the earlier Smith patent is one year later, 15 December 1993.

[8] All of the representative claims were filed after the critical date.

Prior to the critical date, Enzo did not present a claim directed to a method or system for determining the sequence of a nucleic acid.<sup>67</sup>

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<sup>62</sup> *Berman*, 291 F.3d at 1352 (endorsing priority for threshold issues, but affirming that the board may choose the order in which motions are addressed); Bd.R. 125(a).

<sup>63</sup> 35 U.S.C. 135(a) ("The Board...may determine questions of patentability.")

<sup>64</sup> Paper 87 (CIT Reply 7), Apdx. 2, mat'l fact 4 (admitted). For this motion, all references to the material facts are to this appendix.

<sup>65</sup> Mat'l fact 6 (admitted).

<sup>66</sup> Mat'l facts 25-27 (admitted).

<sup>67</sup> Mat'l fact 34 (admitted).



Moreover, prior to the critical date, Enzo did not present a claim directed to detecting non-radioactively labeled nucleic acid fragments in a sequencing gel.<sup>68</sup>

The earlier Smith patent has apparatus claims, while the involved Smith patent has method claims. This division was the result of a restriction requirement. The examiner in making the requirement held that the apparatus and method claims could be used in "materially different" ways.<sup>69</sup>

CIT has provided a side-by-side comparison of an apparatus claim from the earlier Smith patent with two method claims from the involved Smith patent, one of which is the count.<sup>70</sup>

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<sup>68</sup> Mat'l fact 35 (admitted).

<sup>69</sup> Mat'l fact 74 (admitted in form).

<sup>70</sup> Paper 46, apdx. 3.

Claim 14 of '058 Patent (count)	Claim 1 of '534 Patent	Claim 28 of '058 Patent
A method of determining the sequence of a polynucleotide by analyzing polynucleotide fragments generated by a polynucleotide sequencing technique,	A novel system for the electrophoretic analysis of oligonucleotide fragments produced in sequencing operations comprising:	A method for determining the sequence of a polynucleotide which comprises:
each of said polynucleotide fragments being tagged with a chromophore or fluorophore, comprising:	a source of chromophore or fluorescent tagged oligonucleotide fragments, said chromophore or fluorophore being distinguishable by its spectral characteristics,	providing polynucleotide fragments tagged with chromophores or fluorophores, wherein the chromophores or fluorophores are distinguishable from others by their spectral characteristics;
introducing the tagged polynucleotide fragments into an electrophoretic medium; separating the tagged polynucleotide fragments in said electrophoretic medium using an electrophoretic procedure capable of resolving said polynucleotide fragments differing in length by a single nucleotide;	a zone for containing an electrophoresis medium, means for introducing said tagged oligonucleotide fragments to said zone; and	resolving the polynucleotide fragments by electrophoresis; and
detecting the separated tagged polynucleotide fragments by means of the chromophore or fluorophore; and determining the polynucleotide sequence from the polynucleotide fragments detected.	photometric means for monitoring and distinguishing said tagged DNA fragments upon separation in said medium.	detecting the resolved fragments by means of the chromophores or fluorophores, and thereby determining the sequence based on the polynucleotide fragments detected.

[9] The apparatus claim and involved claim 28 are essentially the apparatus and method analogs of each other, respectively.

[10] Involved claim 14, the count, uses more verbiage, but mostly seems to elaborate on inherent aspects of the apparatus and method of the other two claims.

[11] Whether the apparatus and method could be used differently or not, they are substantially the same invention.

## D. Analysis

### 1. *Use of an uninvolved patent*

Enzo argues that CIT is not entitled to repose on an uninvolved patent.<sup>71</sup> As discussed above, repose and patentability are different issues. Repose might be inappropriate based on an uninvolved patent, but § 135(b) unpatentability does not require an interference at all.<sup>72</sup> Hence, the fact that the patent is not involved in the interference is not relevant to the patentability question.

Enzo argues that repose would be inequitable since CIT has enjoyed statutory protection from a double-patenting rejection.<sup>73</sup> Enzo urges that it is disingenuous for CIT to insist the inventions are the same now. As discussed in the next section, CIT's position is consistent with its response to the restriction requirement. In any case, while the statute protects CIT from a double-patenting rejection, it does not prevent adding the earlier Smith patent to this interference.<sup>74</sup> Finally, we are treating the motion as raising a question of patentability, not repose, so CIT's equities are not relevant.

### 2. *Effect of restriction requirement*

Enzo argues that the involved and earlier Smith patents are directed to different inventions by virtue of a restriction requirement.<sup>75</sup> There is no per se rule that restriction requirements define patentably distinct inventions. Indeed, the statute authorizing restrictions assumes otherwise when it

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<sup>71</sup> Paper 74 at 3-6.

<sup>72</sup> *McGrew*, 120 F.3d at 1239 (affirming ex parte § 135(b) rejection).

<sup>73</sup> Paper 74 at 6-7.

<sup>74</sup> 35 U.S.C. 135(a), however, only permits adding an "unexpired patent" to the interference.

<sup>75</sup> Paper 74 at 4-6.

provides a safe harbor against double-patenting rejections between applications resulting from a restriction requirement.<sup>76</sup> The safe harbor would be unnecessary if restrictions always resulted in patentable distinctness. Rather, the restriction requirement has long been recognized as an administrative tool<sup>77</sup> with an ambiguous relationship to patentability. As the Supreme Court has explained:<sup>78</sup>

It is difficult, perhaps impossible, to lay down any general rule by which to determine when a given invention or improvements shall be embraced in one, two, or more patents. Some discretion must necessarily be left on this subject to the head of the Patent Office. It is often a nice and perplexing question.

CIT cites *Leonard v. Everett*<sup>79</sup> for the proposition that method and apparatus claims can be substantially the same invention for the purposes of evaluating whether claims are time-barred.<sup>80</sup> *Leonard* was an appeal to the Court of Appeals of the District of Columbia in an interference. Leonard had two patents as a result of a division.<sup>81</sup> Everett had copied claims from the apparatus patent within two years, but had not copied claims from the method patent within two years.<sup>82</sup> Leonard contended that the claims were

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<sup>76</sup> 35 U.S.C. 121.

<sup>77</sup> *In re Weber*, 580 F.2d 455, 458 (CCPA 1978).

<sup>78</sup> *Bennet v. Fowler*, 75 U.S. (8 Wall) 445, 448 (1869); *see also Weber*, 580 F.2d at 460 (Rich, J., concurring): "Dealing, as it does, with requirements for restriction, § 121 says nothing whatever about the rejection of claims, a matter entirely separate from restriction."

<sup>79</sup> 281 F. 594 (D.C. Cir. 1922).

<sup>80</sup> Paper 46 at 17-18.

<sup>81</sup> 281 F. at 595.

<sup>82</sup> *Id.* at 596.

untimely under *Chapman*, applying a variety of theories.<sup>83</sup> The apparatus claims were plainly timely under *Chapman*, but the method claims were not; rather, the question was whether the method claims were sufficiently like the patent claims to evade estoppel. The court determined that they were substantially the same invention, quoting an Office determination:<sup>84</sup>

The method is inherent in the apparatus and in considering the question of priority, which is the question before us, it is thought safe to say that the one who first invented the apparatus, first invented the method. In reality the invention is integral, although in mental conception it may be more broadly expressed in the method claims. Everett unquestionably has always had the basis for and subject-matter of the method in his application. With this view it would seem absurd to permit him to make the apparatus claims and not permit him to make the method claims.

Enzo notes that the opinion is not technically binding authority and thus should not have been used.<sup>85</sup> It is true that board rules discourage the citation of non-binding authority, but they do not prohibit it.<sup>86</sup> In any case, the court's opinions from this period deserve a special respect since the court then served the function now filled by the Federal Circuit in reviewing

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<sup>83</sup> *Id.*

<sup>84</sup> *Id.* *Leonard*, of course, is addressing the second ("safe harbor") part of the test: whether the timely claim is "such a claim" as the present contested claim. The phrase "such a claim", however, refers to the "claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent" in the first ("trigger") part of the test. Consequently, *Leonard* is relevant to the first part of the test as well.

<sup>85</sup> Paper 74 at 18-19.

<sup>86</sup> Bd.R. 12(b) ("Non-binding authority should be used sparingly."); Paper 2 (SO) ¶12.3 ("Decisions of other federal courts and non-precedential decisions of the Board may be cited, but are not binding precedent.").

interference decisions. While the Federal Circuit has not adopted the court's decisions as precedent,<sup>87</sup> it is particularly authoritative even if not binding on questions touching on interferences before the creation of the Federal Circuit. Indeed, the Federal Circuit's main predecessor in patent law cited to this very case several times, once as recently as 1977 for this very proposition (albeit to distinguish it factually).<sup>88</sup>

The question before us is whether on the facts of this case the apparatus and method claims are directed to substantially the same invention. As we found above, they are. While the examiner, in making the restriction, contended that the claimed subject matter had "materially different" uses, it does not follow that they are materially different inventions.<sup>89</sup> The difference could simply reflect that an apparatus and method are different aspects of the same invention.<sup>90</sup> When the resulting claims are compared side-by-side, the restriction requirement appears to be a matter of administrative convenience rather than a substantive decision on the merits.<sup>91</sup>

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<sup>87</sup> *South Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (in banc).

<sup>88</sup> *Corbett*, 568 F.2d at 766.

<sup>89</sup> *Cf. Webster Elec. Co.*, 264 U.S. at 464-65 (explaining that the barred claims resulted from an amendment with "new and broader claims" than those that had interfered).

<sup>90</sup> Mat'l fact 74 (admitted in form); Exh. 1060 (Exam'r action of 01/04/90) at 2.

<sup>91</sup> In any case, we are not bound by an ex parte determination. *Glaxo Wellcome, Inc. v. Cabilly*, 56 USPQ2d 1983, 1984 (BPAI 2000) (explaining why examiner decisions are not binding on the board in an interference).

Enzo argues that, since CIT did not traverse the restriction requirement it effectively conceded the materiality of the difference.<sup>92</sup> Even by Enzo's account of the facts, CIT did traverse the merits of the restriction. CIT's efforts stopped short of a petition for supervisory review,<sup>93</sup> but that may reflect a practical decision rather than a concession on the merits. In an analogous context, the Federal Circuit has held that the filing of a terminal disclaimer to resolve a double-patenting rejection does not operate as a concession on the merits of the rejection.<sup>94</sup>

### 3. *Safe harbor*

CIT has presented a facial case for holding Enzo's claims barred in view of the earlier Smith patent. Enzo has not demonstrated that it had "such a claim" before the critical date that the earlier Smith patent established.

### E. Holding

On the basis of the evidence and arguments before us, the earlier Smith patent bars Enzo's involved claims.

## IV. CIT MOTION 12—EXCLUDING EVIDENCE

Enzo seeks reconsideration<sup>95</sup> of the portion of a single-judge order sanctioning Enzo for cross examination misconduct.<sup>96</sup> Specifically, the testimony of Dr. Roe was to be accorded no weight when it conflicted with

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<sup>92</sup> Paper 74 at 4-5 & 9.

<sup>93</sup> 37 C.F.R. § 1.144.

<sup>94</sup> *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir 2007).

<sup>95</sup> Paper 118.

<sup>96</sup> Paper 117.

other evidence of record.<sup>97</sup> Enzo's prejudice is hypothetical since Dr. Roe's testimony was treated above, but held to be unpersuasive in view of the record as a whole. Since exclusion of the testimony essentially operates as an alternative basis for granting CIT motion 4, however, we will reconsider the order for an abuse of discretion.<sup>98</sup>

Enzo is concerned that exclusion of the Roe testimony might lead to an inadequate apprehension of scientific fact.<sup>99</sup> Assuming this misapprehension occurs, it would simply be the consequence of exclusion. Sanctions can be dispositive directly or indirectly.<sup>100</sup> An exclusion can deprive a party of critical evidence. This concern does not demonstrate an abuse of discretion.

Enzo is concerned that the exclusion is overbroad since not all of Dr. Roe's testimony was addressed in cross examination that resulted in the sanction and not all of the cross examination was tainted by the misconduct identified in the order.<sup>101</sup> Choice of sanction is typically left to the discretion of the tribunal.<sup>102</sup> Enzo has not pointed to any authority requiring a tribunal to parse testimony in this manner. Indeed, the misconduct in question demonstrates the problem with the approach Enzo suggests. The misconduct was not a single transgression but rather frequent, pervasive albeit minor abuses that affected the tenor of the entirety of the cross examinations. It is

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<sup>97</sup> *Id.* at 7 (also denying CIT's motion to exclude the evidence entirely).

<sup>98</sup> Bd.R. 125(c)(5).

<sup>99</sup> Paper 118 at 2-4.

<sup>100</sup> Bd.R. 128(b) (listing sanctions including adverse judgment).

<sup>101</sup> Paper 118 at 4-5 and 7-9.

<sup>102</sup> *Bender v. Dudas*, 490 F.3d 1361, 1366 (Fed. Cir. 2007) (affirming exclusion of a patent practitioner for misconduct), *citing* 5 U.S.C. 706 and *Butz v. Glover Livestock Comm'n Co.*, 411 U.S. 182, 185-86 (1973).



impossible to say what the cross examination would have covered with more time and cooperation rather than interruption and vexation.

Enzo states that the order misapprehended Dr. Roe's comment about hitting someone. Specifically, Enzo explains that the comment was a jest aimed at Enzo's counsel rather than a threat aimed at CIT's counsel.<sup>103</sup> The order never says that Dr. Roe threatened Enzo's counsel. It says:<sup>104</sup>

There is some even [sic, even some] indication that the tone set by counsel affected the behavior of the witness.<sup>21</sup>

<sup>21</sup> Exh. 2286 at 209:5-6 ("Do you want me to hit him? Should I hit him? Should I hit him?").

The opinion does not characterize the behavior beyond indicating that it was inappropriate. Even were we to accept Enzo's explanation, Dr. Roe's jest was remarkable in the context of a contentious cross examination, suggesting a slippage beyond good judgment. In any case, the order hardly rests on what it characterizes as "some...indication" of a witness behavior problem. The order is expressly grounded on a pattern of counsel's behavior.

Enzo stresses that CIT suffered no prejudice during the cross examinations.<sup>105</sup> The order explicitly notes that no single incident was sufficiently gross to warrant the sanction, but based the sanction on the patten of misconduct.<sup>106</sup> As noted above, it is impossible to say how

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<sup>103</sup> Paper 118 at 5-6.

<sup>104</sup> 117 at 5.

<sup>105</sup> Paper 118 at 6-7.

<sup>106</sup> *Nilssen v. Osram Sylvania, Inc.*, 528 F.3d 1352, 1359 (Fed. Cir. 2008) (holding case exceptional not for a single instance of misconduct but for the very multiplicity of instances of minor misconduct).

differently the cross examinations would have proceeded in the absence of coaching and other misconduct.

Enzo has not identified an abuse of discretion warranting modification of the sanction.

## V. ENZO MOTION 1—UNDESIGNATING CLAIMS

### A. Introduction

Enzo moves to have its involved claims 1411-1487, 1490-1491, 1493-1499, 1504-1516, 1518, 1520-1525, 1527, 1530-1539, 1541, 1544-1568, 1570-1581, 1705-1718, 1727, 1730-1731, 1749-1757, 1760-1765 and 1784-1794 designated as not corresponding to the count.<sup>107</sup> CIT does not oppose.<sup>108</sup> Whether opposed or not, a motion must be substantively sufficient to justify relief.<sup>109</sup> Enzo was authorized to address only the independent claims to keep the volume of briefing manageable.<sup>110</sup> A claim properly corresponds to the count if the subject matter of the count, taken as prior art, would have anticipated or rendered obvious the subject matter of the claim.<sup>111</sup>

### B. Claims 1411, 1705, 1706, 1712, 1784 and 1785

These claims are said to be directed to detecting a nucleic acid of interest. Enzo has pointed out differences between the subject matter of

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<sup>107</sup> Paper 37 (Enzo mot. 1 (corrected)) at 2.

<sup>108</sup> *Id.*

<sup>109</sup> Bd.R. 121(b) (movant has burden to justify relief); *Johnson & Johnson Consumer France SAS v. Indena S.p.A.*, 84 USPQ2d 1925, 1926-27 (BPAI 2006) (declining to change the count despite lack of opposition).

<sup>110</sup> Paper 25 (order) at 6.

<sup>111</sup> Bd.R. 207(b)(2).

these claims and of the count, which is directed to sequencing.<sup>112</sup> Enzo relies on the testimony of James J. Donegan to show that in view of these differences, those in the art at the time of filing would not have considered the claimed subject matter to have been obvious.<sup>113</sup> While there is a facial inconsistency between Enzo's argument here and elsewhere in the record regarding detection versus sequencing, for these claims Dr. Donegan's testimony is more persuasive than extrapolated admissions regarding other claims. The cited evidence of record better supports a conclusion that these claims would not have been anticipated or rendered obvious by the subject matter of the count.

C. Claims 1474, 1475, 1708 and 1709

These claims are said to be directed to identifying a chromosome of interest. Again, Enzo notes differences from the count, in view of which Dr. Donegan testifies that those in the art would not have considered the claimed subject matter obvious.<sup>114</sup> The cited evidence of record better supports a conclusion that these claims would not have been anticipated or rendered obvious by the subject matter of the count.

D. Claims 1476 and 1710

These claims are said to be directed to determining chromosome number in interphase cells. Again, Enzo notes differences from the count, in view of which Dr. Donegan testifies that those in the art would not have considered the claimed subject matter obvious.<sup>115</sup> The cited evidence of

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<sup>112</sup> Paper 37 at 3.

<sup>113</sup> *Id.* at 5.

<sup>114</sup> *Id.* at 5-7.

<sup>115</sup> *Id.* at 7-9.

record better supports a conclusion that these claims would not have been anticipated or rendered obvious by the subject matter of the count.

E. Claim 1473<sup>116</sup> and 1707

Claims 1473 and 1707 relates to a process for determining whether the number of copies of a particular chromosome in a cell is normal or abnormal. Again, Enzo notes differences from the count, in view of which Dr. Donegan testifies that those in the art would not have considered the claimed subject matter obvious.<sup>117</sup> The cited evidence of record better supports a conclusion that these claims would not have been anticipated or rendered obvious by the subject matter of the count.

F. Claim 1711

Claim 1711 relates to a process for preparing a labeled oligo- or polynucleotide of interest. Again, Enzo notes differences from the count, in view of which Dr. Donegan testifies that those in the art would not have considered the claimed subject matter obvious.<sup>118</sup> The cited evidence of record better supports a conclusion that this claim would not have been anticipated or rendered obvious by the subject matter of the count.

G. Holding

On the basis of the arguments and cited portions of the record, Enzo has justified the designation of these claims as not corresponding to the count.

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<sup>116</sup> Enzo indicated that it intended to address the separate patentability for claim 1473, *id.* at 1 n.1, but never actually does so. We exercise our discretion to treat it with claim 1707, which appears to contain the same contested limitation.

<sup>117</sup> *Id.* at 9-11.

cc:

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<sup>118</sup> *Id.* at 11-12.